Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane, Room 1061
Rockville, MD 20852

December 20, 2001

Re: Dockets OOD-1543 and OOD-1538

Dear Sir or Madam:

Eastman Kodak Company believes that added guidances for 21CFR Part 11 as published in the Public Docket as OOD-1543 and OOD-1538 are an essential aid to regulated industries to comply with FDA records regulations in a consistent and least burdensome way. We would, therefore, like to offer the following comments for FDA's consideration prior to approving these Guidances.

BACKGROUND

FDA's Final Rule for Electronic Records and Electronic Signatures became effective August 20, 1997. FDA has acknowledged a large gap between the Rule's requirements and the ability of regulated industry to understand the Rule and implement appropriate solutions. Accordingly, on July 21, 1999, FDA issued Compliance Policy Guide 7153.17, tempering enforcement actions based on good faith efforts and considering the:

- Nature and extent of Part 11 deviation(s)
- Effect of the deviation on product quality and data integrity
- Adequacy and timeliness of planned corrective actions
- compliance history of the establishment, especially with respect to data integrity

FDA already has guidances on validation and glossary which industry considers are reasonable. We have long relied on CDRH's software guidances "General Principles of Software Validation" and "Off-The-Shelf Software Use in Medical Devices." Eastman Kodak Company feels that any new guidances for Part 11 should incorporate counterpart guidances thereby harmonizing rather than fragmenting the process of understanding compliance approaches through overlapping documents.

Comments on Public Docket OOB-1538, Part 11 Validation

Issue 1: Apparent expansion of FDA authority via Guidances

We feel the draft Validation guidance appears to stretch the scope and impact of both the Part 11 Rule and past software guidances beyond their original intent. For example:

- The Part 11 Guidance makes no distinction between validation requirements for electronic records for lower vs. higher risk devices, contrary to the precedent in "General Principles of Software Validation"
- The general language of Section 6.1, Commercial Off the Shelf Software, sets a very high standard for COTS, such as evaluating supplier software development activities and discrediting the value of functional testing. This stance ignores widespread industrial validation practice and is inconsistent with the "Least Burdensome" principles enacted in the Food and Drug Modernization Act of 1997 and voluntary used by FDA for added regulations.
- Section 2.1, Applicability, includes research records among those generally subject to FDA regulation. Within CDRH regulations, research appears in support of PMA devices, a very small portion of all medical device classifications. The more generally regulated CDRH records are design records required for all Class 2 and 3 devices and selected Class 1 devices.

OOD-1538 C10

We believe the Guidance should be thoroughly reviewed and rewritten to make clear that it is not meant to regulate records or record-keeping software beyond the requirements of any predicate rules.

Issue 2: Separation of Infrastructure from Software Validation

We recommend this guidance clearly permit separation of application software validation from IT infrastructure validation. Both are essential to overall operational validation. But in most cases there is little interaction and the activities are frequently conducted by different organizations. Appropriate system integration and stress testing can address any interaction concerns. For example, changing a network router should not necessitate revalidation of all software applications operating over that infrastructure. On the other hand, a major server operating system revision may have an adverse impact on application software and need revalidation.

Eastman Kodak Company recommends that this Guidance recognize that under many circumstances the issues of infrastructure and software validation can be separated.

Issue 3: Technological Neutrality

Part 11 guidances should contain methodologies and technologies used in software records systems. We believe that specificity would hamper the adoption of new technology by restricting the use of new technology until FDA can promulgate new guidance. This would place an added burden on FDA and industry by hampering the ability to bring products and technology essential to the public health to market in a timely and affordable way.

Eastman Kodak Company strongly encourages FDA to avoid making the Part 11 Validation Guidance overly technical and thus a greater burden to itself and industry.

Comments on Public Docket OOB-1538, Part 11 Glossary

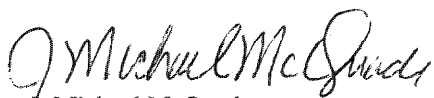
Issue 1: Inclusion/Exclusion Criteria

We feel there is a need for Part 11 Glossary Guidances. However the current Draft Glossary largely consists of definitions taken word-for-word from 21CFR11 Section 11.3: Definitions. The contribution needed by the regulated industry is for unambiguous definitions for terms not clearly defined in existing Guidances and for definitions have differing meanings as used by the various FDA Centers. Numerous examples are in our enclosed line item review of this Guidance.

We recommend deleting terms clearly defined by the Final Rule; recommends adding the definitions for substantive terms in the Compliance Policy Guide and the Part 11 Rule preamble; and clarifying terms used by only some Centers or used differently by the various Centers.

Conclusion

Eastman Kodak Company appreciates the opportunity to comment on FDA Guidances for the Part 11 Glossary and Part 11 Validation. Constructive dialogue between FDA and industry is essential to promote the public health by developing understandable regulations and guidance that protects public health in the least burdensome way to FDA and regulated industry.



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Eastman Kodak Company Comment Form

Date	Document
Dec 19, 2001	Guidance – Electronic Records/ Signatures – Glossary

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
Kodak	General	General	Delete definitions for which the Part 11 Final Rule already provides a definition within section 11.3 Definitions.	Terms that are defined within the Final Rule are already adequately defined and directly accessible. The rationale for a subsequent Guidance is to provide definitions for terms not otherwise covered within a predicate rule or for which the predicate rules of the various FDA centers provide differing definitions.
Kodak	2.1	20-23	Substitute "This guidance applies to manufacturers of finished products regulated under any requirement set forth in the FD&C Act or any FDA regulation." For "This draft guidance applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug and Cosmetic Act (the Act, the Public Health Service Act (PHS Act), or any FDA regulation."	FDA regulates persons, not records. The balance of the wording is unnecessarily redundant.
Kodak	3	52-56	Delete the phrase ""and intended uses"	The use of this phrase suggests that there are or should be approved uses of the covered application similar to the registration processes used to market regulated products. If the phrase "intended use" is included in this guidance document, a definition should be provided that provides a basis for understanding the term in context with electronic records systems.
Kodak	3	52-56	Replace "specifications" with "performance"	As originally stated validation, would require only traceability of specifications to the user needs without performance testing.
Kodak	3	73-82	Delete "The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark."	This latter definition is a form of electronic signature, though not a digital signature. Including this definition creates confusion.
Kodak	3	83		
Kodak	3	New	Add the Coalition remarks differentiating between Data Records and Document Records.	Requirements for these two record types differ significantly. Furthermore the various FDA centers differ in the requirements contained in their predicate rules concerning these record types. Finally the approaches to appropriate validation vary depending on the record type.

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Commenter	**Section**	**Paragraph Figure/ Table Line No.**	**Proposed Change**	**Comment/ Rationale**	
Kodak	3	New	Add the following definition of "audit trail:" "Audit Trail for Electronic Records – an automatically generated electronic record which is an accurate and secure log of each change to an electronic record showing who made the change, what was changed and the date and time of the change which does not obscure prior information."	There is no definition of audit trail within the Final Rule's definitions, yet this is an essential element of the Rule and subsequent Guidance.	
Kodak	3	New	Add the following definition of "legacy system." "Legacy Systems- Computer systems that were being used by an FDA regulated firm for compliance with GxP requirements before the enactment of Part 11 and which therefore may need to be replaced or upgraded with systems that meet business needs and are both GxP and Part 11 compliant."	The definition of Legacy System is not in the Final Rule, but is an important part of manufacturer's compliance planning and execution. It is an important component of the Part 11 Compliance Policy Guide and the Preamble to the Final Rule.	
Kodak		New	**Electronic Identification** - A unique identifier that would distinguish an individual in the automated computer system to allow the individual to be recognized through an audit trail. It is not intended to be an electronic signature		
Kodak		New	**Hybrid System** - a combination electronic/paper based system. An example of a hybrid system is a document control system utilizing electronic storage for records but uses a paper change control process with traditional handwritten signatures for approval of changes. (Part 11 training)	This term was not used in 21 CFR Part 11 Final Rule. However, the concepts have been discussed in Part 11 training, the preamble and discussions of previous drafts.	
Kodak		New	Add a definition for **Metadata as follows:** **Metadata** - Data about data that can be used to establish source, context, location, authenticity, and similar characteristics of an electronic record without being part of the record itself.		
Kodak	2.1	20	Eliminate the word "persons"	Some records are automatically generated by the system or equipment, like audit trails.	

Comment Form

Date	Document
Nov 5, 2001	Guidance – Electronic Records/ Signatures – Validation

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
Kodak	Purpose	5-6	Replace "It may also assist FDA staff who apply part 11 to persons who are subject to the regulation." With "It may also assist FDA staff who review initiatives associated with this regulation."	FDA staff do not directly apply regulations. They do however review materials created by persons responsible for regulated records. The suggested wording is a more accurate way to express this concept.
Kodak	Scope	13	Delete "..and compatible with FDA's public health responsibilities."	This clause adds nothing of substance to the Guidance. The prime audience is the regulated industry, who create electronic records to conduct their business proposes, not solely to comply with public health responsibilities.
Kodak	Scope	14-15	Delete the sentence "Electronic record and signature systems consist of both manual procedural controls and technical controls implemented through computer systems."	This restatement of the Guidance adds no value to the concept of validation and is not linked to the content of the rest of this paragraph.
Kodak	2.1	24-25	Delete the sentence "Any requirements set forth in the Act, PHS Act, or any FDA regulation, with the exception of part 11, are referred to in this document as predicate rules." Insert after the first sentence "(also referred to as Predicate Rules)"	The definition is appropriately included in the part 11 Glossary and this Guidance appropriately cross-references that Glossary.
Kodak	2.1	26	Delete the sentence "Most predicate rules are contained in Title 21 of the Code of Federal Regulations."	This is unnecessary in the context of the first two paragraphs of this Guidance.
Kodak	2.1	27	Either delete the sentence beginning with " In general...categories." Or at least replace the word "research" with 'development".	The CDRH regulations in general do not include research. Indeed, for the medical device industry, the Agency has only recently extended to the context of "design," which is a development activity, via the Oct 7, 1996 revision to the device Quality System Regulation. It is thus not generally applied that Predicate Rules extend to "research." Making that statement in this Guidance would appear to be an expansion of FDA's authority.
Kodak	2.2	32-38	Delete entire section titled "2.2 Audience"	This is redundant to the lines 4-6 of the Purpose. If the Agency feels this is a more accurate and appropriate statement, then lines 4.6 may be deleted but lines 37 and 38 should be formatted as a bullet like the other persons who may wish to use this Guidance.
Kodak	5.1	51-53	Replace: "Regardless of whether the computer system is developed in-house, developed by a contractor, or purchased off-the-shelf, establishing documented end user (i.e., a person regulated by FDA) requirements is extremely important for computer systems validation." With: ""Regardless of whether the computer system is developed in-house, developed by a contractor, or purchased off-the-shelf, establishing software design specifications is extremely important for computer systems validation."	We suggest that defining the task, developing a set of documented criteria upon which the system will be developed and tested is more useful that describing who should accomplish the task.

Comment Form

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Commenter	**Section**	**Paragraph Figure/ Table Line No.**	**Proposed Change**	**Comment/ Rationale**	
Kodak	5.1	54	Replace: "Without first establishing end user needs and intended uses, we believe it is virtually impossible to confirm that the system can consistently meet them." With: "Without establishing software design specifications, we believe it is very difficult to confirm that the system can consistently meet them."	We suggest that the source of the design requirement is essentially irrelevant to the applications suitably for use. We believe that the development of software design specifications is a collaborative effort between developers and users. This section could inappropriately focus industry's efforts on creating separate documents, as indicated by the Agency's use of the word "establishing", with respect to "end-user needs" and "intended uses".	
Kodak	5.1	55-58	Replace: Once you have established the end user's needs and intended uses, you should obtain evidence that the computer system implements those needs correctly and that they are traceable to system design requirements and specifications." With: Once you have established software design specifications, you should obtain evidence that the computer system implements those needs correctly and that they are traceable to system design requirements and specifications."	We suggest that the "end user's needs and intended uses" is an inappropriate compartmentalizing of the task of documenting the criteria upon which the system will be developed and tested.	
Kodak	5.1	58-61	Delete: "It is important that your end user requirements specifications take into account predicate rules, part 11, and other needs unique to your system that relate to ensuring record authenticity, integrity, signer non-repudiation, and, when appropriate, confidentiality."	This sentence relates to design of software, not to validation of software, and is thus not directly pertinent to validation guidance.	
Kodak	5.1	61	After "...confidentiality." Add, "Validations performed by OTS vendors can only confirm conformance to their general requirements. The regulated persons needs to show that the system meets intended use requirements."	It is important to recognized that while the vendor may perform a very complete validation the end user still must confirm that their "intended uses" are fulfilled.	
Kodak	5.1	71-83	Delete the entire paragraph.	The list of examples is neither typical nor inclusive. It also includes examples that do not directly relate to a regulatory need, such as scalability. Left stand as is, it creates an expectation that each electronic record system should be assessed for each factor listed before it may be considered appropriately validated.	
Kodak	5.1	84	Delete the word "thorough" to make the sentence read: "We consider documentation to be extremely important to the success of your validation efforts."	The addition of adjectives such as this are unnecessary to give appropriate weight to the issue raised. The statement "extremely important" adequately raises the point.	
Kodak	5.2	84	Replace the first sentence with the following: "It is essential that any validation be documented."	Although the content of this section moves beyond what is needed specifically for validation for Part 11 compliance, it is worth noting the critical nature of documentation,since undocumented validation is equivalent to no validation at all.	

Comment Form

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Kodak	5.4.1	109-111	Replace "..unexpected data entries, error conditions.." with "..anticipated error conditions.." to make the sentence read: "Test conditions should extend to boundary values, **anticipated error conditions,** reasonableness challenges (e.g., empty fields, and data outliers), branches, data flow, and combinations of inputs."	By definition we cannot anticipate "unexpected data entries." What we can do is to assess what either human errors or computer generated error conditions might occur and test to assure that they do not invalidate the use of the system as a regulated electronic record system.	
Kodak	5.4.1	115-116	Add the word "simulate" to make the sentence read: "Installation testing: These tests are performed in the systems use environment under conditions that simulate actual operating conditions."	Until validation is successfully completed it is not appropriate to entrust actual regulated records to the electronic record system. Thus simulations using end users, as contrasted with simulation devices or simulation software, is often employed. Alternatively, the term "installation testing" as used in "General Principles of Software Validation" could be substituted.	
Kodak	5.4.1	118	Remove the words "any latent' from the sentence		
Kodak	5.4.2	126-127	Delete the sentence "This testing usually includes inspection (or walk-throughs) of the program code and development documents."	This point is not a form of Dynamic Testing and is adequately made in section 5.5 Static Verification Techniques.	
Kodak	5.4.3	135-137	Add "when appropriate" to make the first sentence read: "Quantifiable test results should be recorded in quantified rather than qualified (e.g., pass/fail) terms, **when appropriate.**"	As currently worded it could create an expectation that as sensor technology improves, quantification would always be expected, regardless of quality or regulatory benefit. The clarification acknowledges there are circumstances when this effort is not expected.	
Kodak	5.5	138-140	Replace the second half of this sentence to read: "While dynamic testing is an important part of validation, **where possible it should be accompanied by static verification techniques** to demonstrate complete and correct system performance."	As worded this paragraph creates an expectation for COTS that the Agency later acknowledges is rarely achievable. About all you can do with COTS is dynamic testing. COTS suppliers rarely provide source code, and typically when this is done it is restricted to an escrow of source code for use in case of supplier defaulting on the supplier contract. When not so restricted, it is often written to supplier-specific standards that do not permit the regulated persons an opportunity to conduct a meaningful code walk-through.	
Kodak	5.7	157-159	Replace the second sentence with: "Where appropriate to the risks involved, computer system validation should be performed by persons other than those responsible for building the system.	As worded it sets an expectation that a person not responsible for the system will assess all systems. "General Principles of Software Validation" Section IV(H) recognizes that the "software validation effort should be commensurate with the risk associated with the device, the device's dependence on software for potentially hazardous or critical functions and the role of the specific software modules in higher risk device functions." By analogy the current wording does not consider either the risk class of the device nor the risks to health the specific electronic record system may pose.	
Kodak	5.8	163	Replace the first word "Systems" with "Processes"	The word "systems" in this sentence refers to processes or procedures. If left unchanged t could be confused with electronic record systems.	
Kodak	5.8	167	Delete lines 166-167 "Changes that...particularly significant"	The previous sentence states the facts about determining re-validation. This added input is redundant	
Kodak	5.8	179	Replace "performance/reliability losses" with "consistent intended performance or record reliability losses"	As written it could be interpreted to mean the Agency believes that system uptime or speed of execution is a regulated expectation. The suggested wording is more clearly linked to the intent of the Rule.	

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Kodak	5.8	181-182	Replace the last sentence with "Regression testing should be performed when the regression analysis determines it is appropriate."	Regression analysis should determine what would be assessed during regression testing.	
Kodak	6.1	183, and throughout the balance of the document	Replace "end user" with "manufacturer."	End users are not previously used as a noun in this Guidance. The Agency's definition found in section 5.1 lines 52-53 "end user (i.e., a person regulated by FDA)" is inconsistent with industries use of the term in that the users of an application are often not engaged until the electronic record application is in final testing or introduced into production. More over, other organizational entities are typically assigned the responsibilities noted. As such, this re-phrasing appears to create a new class of regulated persons who are expected to perform specific duties as delineated in this Guidance.	
Kodak	6.1	183-185	Delete the first two sentences.	COTS may include routines that do not create records subject to predicate rules and Part 11. As currently stated this would appear to require validation in a regulated sense to the entire electronic record keeping system, not just the regulated portion. The second sentence adds no specific value in the way of Guidance.	
Kodak	6.1	190-192	Delete the reference to "Macros"	Macros are a form of customization and thus unnecessary to convey the intent of the sentence.	
Kodak	6.1.1	196-197	Delete the sentence "If possible, the end user should obtain a copy of the developer's requirements specification for comparison."	This request is rarely possible. It sets an expectation a vast number of commercially acceptable COTS applications cannot meet. Furthermore it does not consider the risk posed by the system being validated. This expectation is thus inconsistent with the principles of the "Least Burdensome Approach" enacted by Congress in the Food and Drug Administration Modernization Act of 1997(FDAMA)	
Kodak	6.1.2	198-208	Replace the entire section with: "Users should infer the adequacy of software structural integrity by considering the following research into the program's history of use: 1. identifying known program limitations 2. evaluating experience of other users 3. identifying known software problems, their resolution and the acceptability of any remaining residual risks."	This entire section introduces new concepts that go beyond prior FDA Guidance contained in "Off-the-Shelf Software Use in Medical Devices"(OTS) Sept 9, 1999 and "General Principles of Software Validation"(General Principles), June 9, 1997 or that extend concepts significantly beyond the expectation of those Guidances. For one it does not contain the concept of risk analysis/hazard analysis, either based on the risks or hazards of using the device or the risks that errors in the electronic record system may present contained in the General Principles guidance. As currently worded it implies that all known software problems be resolved, even if these problems present no risk to public health. Secondly it creates and expectation for supplier software development auditing for all electronic record systems that was previously only expected by the agency for "Major Level of Concern" devices in OTS. We believe the current draft is inconsistent with the principles of "Least Burdensome" as contained in FDAMA.	

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Kodak	6.1.3	210/218	Replace sentence starting with "Functional testing of software that covers all functions of the program should be conducted. For the program source code or development documentation (e.g., for most commercial off-the-shelf software, and for some contracted software,).functional testing might also be warranted where general experience with a program is limited, or the software performance is highly significant to data/record integrity and authenticity." .	There should be a linking of the requirements to the testing. One of the primary premises of validation is to ensure requirements are met and one of the tools is proper testing.	
Kodak	6.1.3	216-217	Replace the last clause with "or the electronic data/record's integrity or authenticity poses unacceptable risks to public health."	The term "highly significant" is not well understood or previously defined. The concepts of risk to public health are however extensively use in prior regulations and Guidances.	
Kodak	6.1.3	217-218	Delete the sentence: "Note, however, we do not believe that functional testing alone is sufficient to establish software adequacy."	Again this statement goes beyond the expectations contained in the OTS guidance, placing a higher burden on electronic records systems than on Major Level of Concern software in medical devices. The difficulties in conducting code review have been previously noted. This statement negates the content of the entire paragraph to which it is appended.	
Kodak	6.2	219	Delete the phrase "in electronic recordkeeping" to make the sentence read: "We recognize the expanding role of the Internet in the context of part 11."	The phrase adds nothing to the meaning of the sentence and is previously undefined.	
Kodak	6.2	220	Delete the term "Vital" to make the sentence read: "Records such as clinical data reports or batch release approvals can be transmitted from source to destination computing systems by way of the Internet."	As currently worded it seems to imply that only "Vital" records may be transmitted, leaving the term "vital" undefined.	
Kodak	6.2.1	238-239	Replace the last sentence with "Where appropriate delivery acknowledgements such as receipts or confirmations."	As written it appears to preclude the use of Internet delivered acknowledgements. Since the most efficient form of confirmation would be one executed across the sending medium, the option needs to be maintained to accept such acknowledgements when they can be appropriately controlled.	